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Application No.: 09/961091Case No.: 54404US008

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**Remarks**

Claims 36 to 60 are pending and remain under consideration.

Applicants respectfully request reconsideration of the application in view of the following remarks.

**§ 102 Rejections****Rejections based on U.S. Pat. No. 5,038,798**

Claims 36-38, 49-51, 59, and 60, of which claims 36 and 51 are independent, stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,038,798 ("Dowdy"). The rejection is improper and should be withdrawn.

M.P.E.P. § 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Claim 36 recites: A medical treatment article comprising:

at least one fluid control film component having *at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area.* (emphasis added)

Claim 51 recites: A method of using a medical article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area, the method comprising:

placing the medical article in proximity to a medical treatment site so that *the fluid control film component is capable of providing fluid communication between the medical treatment site and the remote area;* and

allowing the medical treatment article to *transport fluid between the medical treatment site and the remote area.* (emphasis added)

Dowdy cannot anticipate claim 36, claim 51, or any claim directly or indirectly dependent from claim 36 or claim 51 because Dowdy fails to set forth each and every element of the claims.

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Specifically, Dowdy fails to set forth a fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area.

The Office Action cites column 1, lines 49-61, column 2, lines 60-64, and column 3, lines 6-11 of Dowdy as providing teaching that anticipates the instant claims. However, the cited passages fail to support the position stated in the Office Action.

The portion of column 1 of Dowdy cited in the Office Action teaches that the drape contains a fluid collection pouch having a top layer, a bottom layer, a fenestration, and an adhesive layer. The portion of column 2 of Dowdy cited in the Office Action teaches that fluid collection pouch includes a fluid collection portion and an incise insert; the fluid collection portion may be made from a translucent plastic film having a micro embossed surface. The portion of column 3 of Dowdy cited in the Office Action teaches that the top layer of the fluid collection portion has a cutaway, an approximately square shaped opening surrounded by a textured reinforcement area.

Nothing in the cited passages, or anywhere else in Dowdy, sets forth a fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area. Applicants define a fluid control film as a film or sheet or layer having at least one major surface comprising a microreplicated pattern capable of manipulating, guiding, containing, spontaneously wicking, transporting, or controlling, a fluid (page 7, lines 19-21), and define "microreplication" as the production of a structured surface through a process where the structured surface features retain an individual feature fidelity during manufacture (page 7, lines 25-27).

Dowdy teaches that the fluid collection portion may be made from a film having a micro embossed surface. The micro embossed surface fails to anticipate Applicants' fluid control film component for at least two reasons. First, the micro embossed surface fails to permit transport of fluid between a medical treatment site and a remote area. The fluid collection portion – the only portion of the Dowdy article described as having a micro embossed surface – is the remote area of the Dowdy article. Thus, the micro embossed surface merely permits fluid transport *within* the remote area; it does not permit transport of fluid *between* the medical treatment site and the remote area, as recited in the claims. Second, the surface is described merely as micro embossed.

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Thus, Dowdy provides fails to set forth that the structured surface features retain an individual fidelity during manufacture. While a microreplicated surface may be manufactured by embossing, the fact that a surface is embossed – by, for example, micro embossing – does not necessarily identify the surface as microreplicated.

Dowdy fails to set forth, either expressly or inherently, each and every element of claims 36 and 51. Therefore, Dowdy cannot anticipate either of claims 36 and 51. Each of claims 37, 38, 49, and 50 depends, directly or indirectly, from claim 36 and is, therefore, patentable over Dowdy for at least all of the reasons that claim 36 is patentable over Dowdy. Each of claims 59 and 60 depends, directly or indirectly, from claim 51 and is, therefore, patentable over Dowdy for at least all of the reasons that claim 51 is patentable over Dowdy.

The rejection of claims 36-38, 49-51, 59, and 60 under 35 USC § 102(b) as being anticipated by Dowdy is improper and should be withdrawn.

#### **Rejections based on U.S. Pat. No. 5,895,380**

Claims 36-38, 45-48, and 51-54, of which claims 36 and 51 are independent, stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,895,380 ("Turi"). The rejection is improper and should be withdrawn.

Turi fails to set forth, either expressly or inherently, each and every element of the claims. Specifically, Turi fails to set forth a fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area.

The Office Action appears to assert that the perforations in the film 50 constitute "a plurality of channels" as recited in the claims. Applicants' previous response, dated October 13, 2004, rebutted the exact same argument with respect to perforated films described in the Patel reference (U.S. Pat. No. 5,632,731).

Briefly, the channels in Applicants' disclosure are described as "precisely replicated from a predetermined pattern and form a series of individual open capillary channels that extend along a major surface." (page 8, lines 12-14, emphasis added). Turi describes a sanitary napkin that includes a perforated film. The perforations are not capillary channels that extend along a major surface. Instead, they are merely holes in the film that permit diffusion through the film.

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Also, Turi fails to describe a medical treatment article that permits transport of fluid *between a medical treatment site and a remote area*. The Office Action seems to suggest that the diffusion of fluid through the perforated film and into the absorbent body 42 constitutes fluid transport to a remote area. Again, as discussed in Applicants' response dated October 13, 2004, Applicants' disclosure uses the term "remote" refers to a location other than directly over a medical treatment site. Applicants' disclosure specifically distinguishes the "fluid transport to a remote area" feature from medical articles such as those described in Turi at page 5, lines 12-15, as follows: "This embodiment functions in an opposite manner to conventional wound dressings that place an absorbent over the wound itself." While the article of Turi is not described as a wound dressing, it is nevertheless designed so that the absorbent body is placed directly over the source of the fluid to be absorbed by the article. Thus, the distinction made in Applicants' disclosure is just as relevant to the article of Turi as to convention wound dressings.

As with the rejections based on Dowdy, the passages of Turi cited in the Office Action as providing teaching that anticipates the instant claims utterly fail to set forth, expressly or inherently, a fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area.

Turi fails to set forth, either expressly or inherently, each and every element of claims 36 and 51. Each of claims 37, 38, and 45-48 depends, directly or indirectly, from claim 36 and is, therefore, patentable over Turi for at least all of the reasons that claim 36 is patentable over Turi. Each of claims 52-54 depends, directly or indirectly, from claim 51 and is, therefore, patentable over Turi for at least all of the reasons that claims 36 and 51 are patentable over Turi.

The rejection of claims 36-38, 45-48, and 51-54 under 35 USC § 102(b) as being anticipated by Turi is improper and should be withdrawn.

### § 103 Rejections

Claims 39-44 stand rejected under 35 USC § 103(a) as being unpatentable over Turi. The Office Action states that Turi teaches an embossed film and that the limitations of claims 39-44 are obvious design choices.

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Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness. § 706.02(j) of the M.P.E.P. states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference(s) or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art reference must teach or suggest all of the claim limitations.

Each of claims 39-44 depends, directly or indirectly from claim 36. As discussed above, Applicants submit that Turi fails to set forth each and every limitation of claim 36 and, therefore, fails to set forth each and every element of claims 39-44 as well. Specifically, Turi fails to set forth a fluid control film component as defined in Applicants' disclosure, and also fails to set forth that the film is capable of permitting transport of fluid between a medical treatment site and a remote area.

First, Turi contains no teaching or suggestion that the embossed film complies with the definition of fluid control film discussed above and provided in Applicants' disclosure at page 7, lines 19-21. Second, even if, for the sake of discussion, the embossed film could be considered a fluid control film according to Applicants' disclosure, the embossed film fails to permit fluid transport between a medical treatment site and remote area. The fluid transport permitted by the embossed film is either (a) diffusion *through* the film, or (b) transport *within* the absorbent body, neither of which corresponds to "fluid transport between a medical treatment site and remote area." Reasons why diffusion through the film fails to correspond to fluid transport to a remote area are discussed above and previously presented in Applicants' response dated October 13, 2004. Reasons why transport within the absorbent body fails to correspond to fluid transport to a remote area were (a) presented by Applicants and acknowledged by the Examiner in the parent case, which resulted in the granting of U.S. Pat. No. 6,420,622, and (b) presented again by Applicants' in the present application in a telephonic interview held November 5, 2003 and reiterated in Applicants' Appeal Brief dated July 8, 2004.

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Accordingly, Turi fails to teach or suggest all of the limitations of claims 39-44. Therefore, the rejection of claims 39-44 under 35 USC § 103(a) as being unpatentable over Turi has been overcome and should be withdrawn.

**Conclusion**

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application and allowance of claims 36-60 is requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that doing so may assist prosecution of this application.

Respectfully submitted,

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